DOCUMENTS TO BE SUBMITED FOR APPROVAL OF ADDITIONAL PRODUCT UNDER DRUG LICENSE GRANTED

1. Application (statutory) in Form-24 /27/31/24B/24A/27A/27D/27DA/31A

   duly signed by the Proprietor / Managing Partner / Managing Director/ Person declared as responsible under Sec.34 / Person Authorized by the Board of Directors accompanied by Company Board Resolution

2. Consolidated list of Formulations with packing particulars under each licence separately category wise viz. Tablets, Capsules, Injectables etc.

PRODUCT INFORMATION IN RESPECT OF

Bulk Drugs/ Formulations:

i. Brief Manufacturing procedure of each product

ii. Flow Chart with structural Formula of reactions (for bulk drugs) as per Master Formula record and specifications & analytical procedure of applied products with in-house specification claim.

iii. Copies of monographs for formulations with pharmacopoeial specifications other than IP.

iv. Form 46/ Form 46-A in case of 'New Drugs' under Rule 122E of Drugs and Cosmetics Act and Rules made thereunder/ NOC from CDSCO for specific quantity export of New Drugs.

v. Declaration regarding the Brand Names of the Product. **(in case of Formulations).**

Note: (maximum no. of products in an application – thirty (30).